Section 5 of Traditional 510(K) Submission:

DEC 2 0 2013

510 (K) Summary

This 510(K) Summary of safety and effectiveness information is being submitted in accordance with requirement of 21 CFR807.92

The assigned 5 10(k) Number: K132428

1. Date of Submission: Sept. 11, 2013
2. Submitter / 510(K)Holder

Jiangsu Ideal Medical Science & Technology Co., Ltd.
East Area, Jinfeng Industry Park
Zhangjiagang City
Jiangsu Province,
China 215625

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3. Proposed Device Name

Trade name: Ideal™
Common name: Intramedullary Nail System
Classification Name: Intramedullary fixation rod
Device Class: Class II
Classification Panel: Orthopedic Panel
Product Code: HSB
Regulation Number: 21 CFR 888.3020

4. Predicate Devices

510 (k) Number: K121312
Product Name: Intramedullary Nail System
Submitter: Weigao Orthopaedic Device Co., Ltd.

5. Device Description

The Ideal™ Intramedullary Nail System is intended to provide temporary fracture fixation and stabilization of the tibia. (Simple, compound first- and second-degree tibial shaft fractures, pseudarthrosis and delayed union). It consists of intramedullary nail, locking screw and end cap.

The Intramedullary nail is available in a variety of lengths and diameters to meet assorted anatomical needs. Each of the nails is secured by a series of screws that pass through holes manufactured into the proximal and distal sections of each nail. The locking screw passes through the holes at the proximal and distal sections of intramedullary nail for preventing rotation and axial compression. The end cap which screws into the threaded end of the intramedullary nail provides intraoperative lengths adjustment and prevents tissues growth into nail threads.

All implants of intramedullary nail system are manufactured from Ti-6A1-4V alloy that meets the requirements of ASTM F-136. The materials are widely used in the industry with well-known biocompatibility. No new materials are used in the development of this implant.

6. Indication for Use/Intended Use

The Ideal™ Intramedullary Nail System is intended to provide temporary fracture fixation and stabilization of the tibia. (Simple, compound first- and second-degree tibial shaft fractures, pseudarthrosis and delayed union).

7. Non-Clinical Testing

Bench tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that proposed device complies with the following standards:

ASTM F1264-03 (Reapproved 2007), Standard Specification and Test Methods for Intramedullary Fixation Devices, including the following items:

* Static bending test
* Static torsion test
* Dynamic bending test

ASTM F 543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws- pullout strength, including the following item:

* Pull out test

8. Substantially Equivalent Conclusion

The Ideal™ Intramedullary Nail System has same intended use and similar technological characteristics as the predicate device. The proposed device, the Ideal™ Intramedullary Nail System, is determined to be Substantially Equivalent (SE) to the predicate device, K121312 Intramedullary Nailing System, in respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Jiangsu Ideal Medical Science & Technology Company, Limited
% Ms. Bo Gong
Shanghai Yarui Consultant Company, Limited
Room 503, Building 8, 600 Liu Zhou Road
Shanghai, 200233
China

Re: K132428
Trade/Device Name: Ideal™ Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Codes: HSB
Dated: September 19, 2013
Received: September 30, 2013

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 of Traditional 510(K) Submission:

Indications for Use

510(k) Number: K132428

Device Name: Ideal™ Intramedullary Nail System

Indications For Use:

The Ideal™ Intramedullary Nail System is intended to provide temporary fracture fixation and stabilization of the tibia. (Simple, compound first- and second-degree tibial shaft fractures, pseudarthrosis and delayed union).

Prescription Use___X_____ **AND/OR** **Over-The-Counter Use_____**

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Elizabeth L. Frank -S

Division of Orthopedic Devices